(c) positioning the stent substantially within the prostatic section of the urethra;

(d) monitoring fluid drainage through the stent and the connecting segment, and out of the distal end of the connecting segment located outside of the patient's body;

(e) decoupling the connecting segment from the stent; and

(f) withdrawing the connecting segment completely from the urethra and patient's body.

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REMARKS

Claims 1-9 and 16-18 are withdrawn from consideration but are still pending. Claims 10-15 and 19 are rejected. Applicants hereby amend claims 10, 11, 12, and 19. Claims 13-15 were previously amended in Applicants' Preliminary Amendment filed on April 2, 2001, as were withdrawn claims 1-9 and 16. In compliance with 37 C.F.R. § 1.121(c)(1)(ii), a marked-up copy of the claims is enclosed herewith. A clean copy of pending and examined claims 10-15 and 19 also is enclosed, with all changes incorporated.

Applicants have amended claims 10 and 19 to address existing aspects of those claims, and Applicants submit that those amendments are unnecessary to overcome the rejections.

Applicants submit that no new matter has been added. Support for the amendments to the claims can be found throughout the originally-filed claims and specification, and at least, for example, at pages 9 and 10.

Applicants request reconsideration and allowance of pending and examined claims 10-15 and 19, as amended.

Rejections Under 35 U.S.C. §112, Second Paragraph

Applicants have amended claims 11 and 12 to address these rejections.

Rejections Under 35 U.S.C. §102(b)

Claims 10-12 and 19 are rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,041,092 to Barwick ("Barwick").

Amended independent claim 10 recites a prostatic stent-catheter system for draining fluid from the bladder and through the prostate after prostate treatment. The system comprises a stent and a connecting segment. The stent comprises a body member including a distal terminating

end, a proximal end portion, and a lumen extending within the body member. The body member is sized for placement substantially within the prostatic section of the urethra with the distal terminating end located proximal of the external sphincter.

Barwick at least fails to teach or suggest a stent comprising a body member sized for placement substantially within the prostatic section of the urethra with a distal terminating end located proximal of the external sphincter. Instead, Barwick discloses a urethral catheter with incontinence control and with a tubular member 16 that is inserted into the urethra and that is "sized such that the incontinence valve 60 substantially aligns with the penile meatus." (Col. 6, lines 35-39.) Nothing in Barwick teaches or suggests a stent sized for placement substantially within the prostatic section of the urethra with a distal terminating end located proximal of the external sphincter.

Amended independent claim 19 recites a method of placing such a prostatic stent-catheter system, and thus Barwick also fails to teach or suggest the method of claim 19.

For at least this reason, Applicants submit that amended claims 10 and 19 are patentable over Barwick. Amended claims 11 and 12 depend from claim 10 and are patentable over Barwick for at least the same reason.

Rejections Under 35 U.S.C. § 103(a)

Claims 10-15 are rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 4,955,859 to Zilber ("Zilber") in view of U.S. Patent No. 6,238,430 to Klumb et al ("Klumb").

Amended independent claim 10 recites a prostatic stent-catheter system for draining fluid from the bladder and through the prostate after prostate treatment. The system includes a stent and a connecting segment. The stent comprises a body member including a distal terminating end, a proximal end portion, and a lumen extending within the body member. The connecting segment comprises an elongated body member including a distal end located outside of a patient's body, a proximal end releasably coupled to the distal terminating end, and a lumen which extends within the elongated body member.

Zilber fails to teach or suggest a connecting segment comprising an elongated body member including a proximal end releasably coupled to a distal terminating end of a body

member of a stent. Instead, Zilber describes a stent "pushed out of an accessory casing and into the lumen of a sheath." (Col. 8, lines 14-15.) The stent is then "pushed through the sheath with a flexible rod" and "emerges from the opposite end of the sheath." (Col. 8, lines 16-18.)

Klumb also fails to teach or suggest a connecting segment comprising an elongated body member including a proximal end that is releasably coupled to a distal terminating end of a body member of a stent. Klumb describes a catheter having a "catheter shaft defining three lumens therein" (col. 5, lines 65-66), and a coiled stent "placed in torqued compression onto the catheter shaft" (col. 9, lines 65-66). Klumb describes the stent as wrapped around and coupled to the catheter shaft by both stent ends. (Col. 9, lines 17-30 and col. 10, lines 17-18.) Klumb describes an assembly in which the lumen of the stent surrounds the lumen(s) of the catheter shaft when the stent is coupled to the catheter shaft.

No combination of Zilber and Klumb could possibly have resulted in the system recited in amended claim 10. Each of Zilber and Klumb fails to teach or suggest a connecting segment comprising an elongated body member including a proximal end that is releasably coupled to a distal terminating end of a body member of a stent. As such, the combination could not possibly have resulted in a system as recited in amended claim 10.

For at least this reason, Applicants submit that amended claim 10 is patentable over Zilber and Klumb. Claims 11-15 depend from claim 10 and are patentable over Zilber and Klumb for at least the same reason.

CONCLUSION

In view of the foregoing, Applicants request reconsideration and allowance of pending and examined claims 10-15 and 19 in due course.

Respectfully submitted,

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MARKED-UP COPY OF THE AMENDED CLAIMS

10. A prostatic stent-catheter system for draining fluid from the bladder and through the prostate after prostate treatment, comprising:

(a) a stent comprising a body member including a distal terminating end, a proximal end portion, and a lumen extending within the body member, the body member sized for placement substantially within the prostatic section of the urethra with the distal terminating end located proximal of the external sphincter; and

(b) a connecting segment comprising an elongated body member including a distal end located outside of a patient's body, a proximal end releasably coupled to the distal terminating end ~~of the stent~~, and a lumen which extends ~~extending~~ within the elongated body member and aligns with the lumen of the body member of the stent when the proximal end of the elongated body member of the connecting segment is coupled to the distal terminating end of the body member of the stent to form a single lumen through the prostatic stent-catheter system.

11. The prostatic stent-catheter system according to claim 10 wherein the stent further comprises a retaining member extending from the proximal end portion of the body member of the stent, the retaining member capable of holding the body member substantially within the prostatic section of the urethra.

12. The prostatic stent-catheter system according to claim 10 wherein the stent further comprises a retaining member extending from the proximal end portion of the body member of the stent, the retaining member being collapsible and expandable.

19. A method of placing a prostatic stent-catheter system, comprising the steps of:

(a) providing the prostatic stent-catheter system which comprises:

(i) a stent comprising a body member including a distal terminating end, a proximal end portion, and a lumen extending within the body member, the body member sized for placement substantially within the prostatic section

of the urethra with the distal terminating end located proximal of the external sphincter; and

(ii) a connecting segment comprising an elongated body member including a distal end located outside of a patient's body, a proximal end releasably coupled to the distal terminating end ~~of the stent~~, and a lumen which extends ~~extending~~ within the elongated body member and aligns with the lumen of the body member of the stent when the proximal end of the elongated body member of the connecting segment is coupled to the distal terminating end of the body member of the stent to form a single lumen through the prostatic stent-catheter system;

(b) inserting the prostatic stent-catheter system into the patient's urethra;

(c) positioning the stent substantially within the prostatic section of the urethra;

(d) monitoring fluid drainage through the stent and the connecting segment, and out of the distal end of the connecting segment located outside of the patient's body;

(e) decoupling the connecting segment from the stent; and

(f) withdrawing the connecting segment completely from the urethra and patient's body.